

JAN 14 1999

510(k) Summary

K982630

Trade Name: MedWorks Visualization Insemination Catheter

Sponsor: MedWorks Corp.
2400 Crittenden Drive
Louisville, KY 40217
Registration #1530618

Device Generic Name: Intrauterine Insemination Catheter

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices: Roseff's Double Lumen Standard Intrauterine Insemination Catheter (K884696)
Fertility Technologies, Inc.

Standard Intrauterine Insemination Catheter (K884696)
CCD International

Mini-Embryon Intra Uterine Insemination Catheter (K972823)
A&A Medical, Inc.

Jansen-Anderson Insemination Set (K914150)
Cook Ob/Gyn

Centurion Vaginal Speculum (K897100)
Tri-State Hospital Supply

Galileo Disposable Endoscope (K981928)
Galileo Electro-Optics Corp.

Imagyn MicroSpan Insemination System (970750), MicroSpan Hysteroscope Sheath (K961506) and MicroSpan Hysteroscope (K961688)
Imagyn Medical, Inc.

Product Description:

Malleable catheter with distal side ports and a lumen which can accommodate a fiberoptic device to allow visualization of the interior of the uterus. Allows physician to confirm placement of insemination fluid in the uterine cavity.

Indications for Use:

For use in intrauterine artificial insemination procedures using washed spermatozoa or semen.

Safety and Performance:

Substantial equivalence for this device was based solely on design and performance characteristics; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the MedWorks Visualization Insemination Catheter are equivalent to those of the predicate devices.

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Conclusion:

Based on the indications for use, technological characteristics, and comparison to currently marketed devices, the MedWorks Visualization Insemination Catheter has been shown to be safe and effective for its intended use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pamela L. Papineau
President
Delphi Medical Device Consulting for
MedWorks Corp.
50 Brewster Street
Pawtucket, RI 02860

Re: K982630
MedWorks Insemination Catheter
Dated: November 8, 1998
Received: November 12, 1998
Regulatory Class: II
21 CFR 884.5250/Procode: 85 MFD

Dear Ms. Papineau:

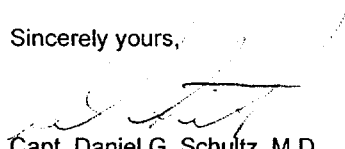
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the -Counter Use

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982630/S⁰⁰¹

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